

## **REMARKS AND RESPONSE TO OFFICE ACTION**

The Claims are amended as noted above. Claims 1-12, 16, 18-37, 44-46, and 49-58 are withdrawn as non-elected inventions. Although original claims 9 and 16 were directed to a polypeptide of alleged invention Group II (classified in 530/350), they each depended from claims alleged to fall in separate (thus, non-elected) inventions. Claims 13-15, and 17, as amended, and claims 38-43 and 47-48 (original) are pending in the instant application. Support for the amendments to the claims can be found in the original specification at, for example, page 5, line 20 to page 7, line 7. The amendments do not constitute new matter. The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

### **I. Miscellaneous Items**

Applicants thank the Examiner for reconsidering the restriction requirement and including both SEQ ID NOs: 5 and 6 in the examined invention. Applicants restate the argument and traverse of record regarding the asserted remaining non-elected inventions as recited in the Restriction Requirement.

Applicants thank the Examiner for considering the Information Disclosure Statements filed on May 30, 2003 and February 21, 2003.

### **II. Objection to the Disclosure**

The pending objection to the disclosure for reciting the term "Drawings" instead of "Figures" on page 8 in the heading, "Brief Description of the Drawings" is believed to be rendered moot by the amendment to the specification.

### **III. Rejections under 35 U.S.C. § 112, second paragraph.**

Claims 9, 13-17, 38-43, and 48 all stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter regarded to be the invention. Applicants respectfully disagree with this basis of rejection.

As an initial note, Applicants believe that the recited rejection of claims 1, 3-14, 20-26, 34, 37, and 40-41 (Office Action, pg. 5, 2<sup>nd</sup> ¶ in Item 5) is in error, as it encompasses non-elected claims and fails to explain the basis for rejection of those claims.

Claim 9 is alleged indefinite for its dependence on a non-elected invention of claim 8. Applicants believe that withdrawal of this claim as a non-elected invention renders this rejection moot, and respectfully request reconsideration and withdrawal of the rejection.

Claim 13 is rejected as indefinite because, allegedly, it is not clear which amino acid sequences are orthologs of SEQ ID NO:5. More particularly the rejection alleges that orthologs of SEQ ID NO:5 cannot be determined because the structural and functional features of SEQ ID NO:5 are not clearly disclosed. Applicants respectfully disagree.

As noted in the Office Action (at pg. 5, 4<sup>th</sup> ¶ in Item 5), Applicants underscore that the specification states that an ABCL ortholog is a polypeptide sequence from another species that corresponds to the ABCL sequence disclosed in, for example, SEQ ID NO:5. Therefore, the term is clear and understood by those of skill in the art. The specification completely and clearly describes orthologs, and further provides an exemplary ABCL orthologs of SEQ ID NO: 5 (murine) in the Examples, and describes how to identify, clone, isolate, and sequence such orthologs (see, for example, Example 2 pp 87-89). Thus, “orthologs” of SEQ ID NO: 5 are clear and definite, and further, can be identified by one of skill in the art, particularly in light of the teaching and guidance found in the specification. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 13 and 14 are alleged indefinite because the ATCC Deposit Nos are not identified with the particular nucleic acid inserts that encode the polypeptide of SEQ ID NO:5. The amendments to the claims render this rejection moot, and further, the Examiner’s attention is drawn to the statement regarding the biological deposits under the Budapest Treaty (Section IV. B., below). Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Claim 14 is further alleged indefinite for recitation of the word “about” in two phrases: “at least about 70% identical,” and “at least about 25 amino acid residues.” Applicants respectfully disagree.

According to the M.P.E.P., when considering relative terminology as used in a claim, the “[a]cceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.” M.P.E.P. § 2173.05(b). Further, the term “about” is a common term used in patent claims and has been held to be clear. M.P.E.P. § 2173.05(b)(A), citing to

*Ex parte Eastwood*, 163 USPT 316 and *W.L.Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). Applicants have provided in the specification detailed discussion regarding how one of skill can determine percent identity, as well as a discussion of the approximate ranges of amino acid residues that can comprise the claimed polypeptide (for example, full length SEQ ID NO: 5 and fragments of at least 25 contiguous amino acid of SEQ ID NO: 5). For example, the specification at page 28, line 10 to page 30, line 14 discusses methods for determining percentage of identity. Further, the number of amino acid residues that can comprise the claimed polypeptide is discussed at, for example page 25, line 12 to page 26, line 19; page 11, line 27 to page 12, line 21; and page 5, line 20 to page 7, line 9. Considering that a number of amino acid modifications that can be made without affecting the activity/function of the claimed polypeptide, Applicants have used relative terminology rather than listing every possible sequence that falls within the scope of the claim. Thus, the specification provides an understanding of the term “at least about” to one of skill in the art, as that term is used in the claims. Applicants, nevertheless, have elected to amend the claims merely in order to expedite prosecution, and respectfully request reconsideration and withdrawal of this rejection.

Claims 14-16 are rejected as indefinite for allegedly not clearly defining the activity of the polypeptide disclosed in SEQ ID NO:5. Applicants respectfully disagree.

As to the rejection of claim 16, the issue is believed moot in light of the withdrawal of that claim as falling within a non-elected invention. As to claims 14-15, the specification provides ample description regarding the activity of the claimed ABCL polypeptide and the ABC transporter family of polypeptides. For example, at pages 89-90 (Example 3), Applicants provide mRNA expression levels in human, monkey, and mouse tissue. The specification also teaches, for example at pages 76, line 28 to page 78, line 12, that ABCL polypeptides may be involved in transport of lipids, including cholesterol; neurosteroids, including DHEA and progesterone; development of thymus, spleen, thyroid, hypothalamus, and ganglia. Thus, the specification provides ample guidance and clarity regarding the activity/function of the claimed polypeptide to one of skill in the art.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claim 14 is rejected as indefinite because the phrase “allelic variant” is alleged not clearly defined so as to allow the metes and bounds of the claims to be determined. Applicants respectfully disagree.

The specification provides a clear and concise definition for the term “variant” (page 12, line 26 to page 13, line 10). From the teaching in the specification, one of skill clearly understands that variants can have from 1-3, 1-5, 1-10, 1-15, 1-20, 1-25, 1-50, 1-75, 1-100 or more than 100 amino acid modifications. Applicants have explicitly detailed a variant of SEQ ID NO: 5 by disclosing the sequence of SEQ ID NO: 6 (46 amino acid N-terminal truncation variant of SEQ ID NO: 5). Thus, in light of the teachings found in the specification, one of skill in the art would have a clear understanding of the term “variant” as it applies to the claimed polypeptides, and thus, the claim particularly points out and distinctly claims the subject matter of the invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claim 15 is rejected as indefinite for allegedly failing to clarify which amino acid residues in SEQ ID NO:5 can be conservatively substituted, while retaining activity. Applicants respectfully disagree.

As with the above discussion regarding the terms “variant” and “about” the specification provides ample guidance to one of skill in the art such that he or she has clear and definite knowledge of the activity of the claimed polypeptide (see argument and citation to specification above). Further a detailed discussion regarding conservative amino acid substitutions is contained in the specification at, for example, page 19, line 18 to page 24, line 21. In particular, Applicants provide guidance for one of skill in determining suitable variants (including conservative amino acid substitutions), for example, at page 22, line 3 to page 24, line 16. In light of all this guidance provided by the specification, one of skill in the art would have a clear understanding of the term conservative substitutions and the relationship to biological activity of the claimed polypeptides.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 16 stands rejected as indefinite for allegedly depending from a non-elected invention of claims 1, 2, and 3. This basis of rejection is believed to be rendered moot in light of the withdrawal of the claims as relating to a non-elected invention.

Claims 17, 38-40, 42, and 43 all stand rejected for depending on allegedly indefinite base claims. This rejection of claims is considered moot, as the claims particularly point out and distinctly claim the

subject matter that Applicants regard as the invention, and in light of the above amendments and arguments.

The claims particularly point out and distinctly claim the subject matter that Applicants regard to be the invention. Accordingly, Applicants respectfully reconsideration and withdrawal of the rejection of claims based on 35 U.S.C. § 112, second paragraph.

#### **IV. Utility Rejections under 35 U.S.C. § 101 and §112, first paragraph.**

A. Claims 9, 13-17, 38-43, 47, and 48 stand rejected under 35 U.S.C. § 101 for allegedly failing to be supported by a specific and substantial utility, or a well established utility. Specifically, the Action asserts that the as-filed specification does not describe a substantial utility for any of the claimed sequences. Applicants respectfully disagree with the Action's assertion that the as-filed specification does not describe a substantial utility for any of the claimed sequences.

Applicants first note that the Office Action asserts the rejection under 35 U.S.C. § 101 follows the *Brenner v. Manson* case (see, e.g., Office action pg. 23, line 1; cites also found at pp. 19 and 21-22). *Brenner v. Manson*, 383 U.S. 519, 148 U.S.P.Q. (BNA) 689 (1966). Applicants respectfully disagree that the issues of utility of the instant application are directly analogous to those of *Brenner*. In *Brenner*, the Supreme Court determined that claims to a chemical process (and not the chemicals themselves) for producing steroids belonging to a particular class of steroids (said class of steroids comprising one known member previously proven effective in inhibiting tumors in mice) lacked patentable utility because the applicants had not disclosed a sufficient likelihood that the steroids produced by the claimed process had similar tumor-inhibiting properties. As stated in *Brenner*, those applicants disclosed nothing more than (a) a process for producing steroids, and (b) that the compounds produced by the claimed process were homologues of a single known compound shown to have tumor-inhibiting properties. The Court's rationale was that excluding others from making, selling, and, most importantly, using the claimed methods would extend patent protection to the undisclosed and unknown compounds. The instant claims are different in almost every way. First, they are composition of matter claims, so there is no similar global inhibition of technological progress as was present in *Brenner*. Second, the instant application affirmatively teaches specific nucleic acid molecules encoding polypeptides that were found to be actually expressed in animals, primarily in thymus, thyroid, and hypothalamus (in human), and spleen, brain, and lung (murine). See, specification page 89, lines 25-29; also page 90, lines 26-30 (monkey and mouse).

Applicants contend, therefore, that the instant application provides the public with a specific benefit (*i.e.*, a particular member of the ABC Transporter superfamily). This situation is wholly unlike the circumstances in *Brenner*, where the chemical process of *Brenner* produced a class of compounds which might not have been produced in nature and which might have had no useful function whatsoever. Under these circumstances, the pending claims do not improperly “engross what may prove to be a broad field.” *Brenner*, 383 U.S. at 534-35.

Applicants next note that the Office Action has asserted that Applicants are required to teach that the claimed polypeptides (and nucleic acids encoding the polypeptides) are diagnostic for a specific disease; have a specific biological activity; or bind to specific ligands. Applicants respectfully disagree, and contend that this is not their burden in satisfying the requirements of 35 U.S.C. § 101.

Such requirements are set forth in the *Revised Interim Utility Guidelines Training Materials* (“Training Materials”). Specifically, applicants are required to demonstrate that the asserted utility is specific and substantial, and if so, whether such asserted utility is credible. Applicants contend that they have met this burden. Under the guidelines of the Training Materials, page 9, Applicants, in the absence of a well-established utility, must first make an assertion of utility for the invention. As the Office has recognized (pages 10-11 of the Office Action), the applicants have asserted that the claimed polypeptides, can be used to treat, diagnose, ameliorate, or prevent a number of diseases, disorders, or conditions associated with ABC transporter polypeptides, for example using the claimed polypeptides to diagnose or treat diseases and conditions involving the thymus and spleen (*e.g.*, lymphoid and myeloid cells such as conditions including, for example, modulation of immune responses, aids, lymphomas, leukemias, neutropenia, anemia, and autoimmune diseases); thyroid (*e.g.*, hypo- and hyperthyroidism); hypothalamus (*e.g.*, obesity, diabetes, reproductive disorders, and energy balance disorders); and ganglia (*e.g.*, neuropathies including, Charcot-Marie-Tooth disease, Dejerine-Sottas syndrome, Guillain-Barr syndrome, diabetic neuropathy, and multiple sclerosis). Specification at pp. 77-78. Thus Applicants have made an assertion of utility for the invention.

Next, the assertion of utility must identify a specific utility. The Training Materials, on page 5, define a “specific utility” as a utility that is specific to the subject matter claimed, as contrasted with a *general* utility that would be applicable to the broad class of the invention. To illustrate the difference between a specific utility and a general utility, the training materials refer to a claim directed to a polynucleotide only having an asserted utility as a gene probe or a chromosome marker, which is a use

that all polynucleotide sequences would have, and therefore, is merely a general utility. As applied to the instant application, the claimed subject matter encompasses polypeptides comprising ABCL sequences, while the broad class of the invention is polypeptide/amino acid molecules. The present application asserts a utility that not *all* polypeptide sequences would have, *i.e.*, not *all* polypeptide sequences could be used to treat, diagnose, ameliorate, or prevent a number of diseases, disorders, or conditions associated with abc transporter polypeptides. Thus, applicants contend that the asserted utility is *specific* to the subject matter claimed, and thus satisfies the first prong of a utility analysis.

Third, the assertion of utility must be substantial. The Training Materials, on page 6, define a “substantial utility” as a utility that has a “real world” use. Members of the ABC transporter protein superfamily are well known and play an important role in multiple disease states and conditions (see specification at page 76, line 10 to page 78, line 26). A member of the ABC transporter protein superfamily has a “real world” use in a number of diseases, disorders, or conditions and thus in treating, diagnosing, ameliorating, or preventing various disease states and conditions associated with atp-dependent translocation of solutes across biological membranes. Thus, applicants contend that the asserted utility is substantial, and thus satisfies the second prong of a utility analysis.

Finally, the assertion of utility must be credible. The Training Materials, on page 5, define a “credible utility” as an assertion of utility that is believable to one of ordinary skill in the art based on the totality of evidence and reasoning provided. Furthermore, the training materials state that a credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. The instant application teaches nucleotide sequences encoding an amino acid sequence for human and murine ABCL polypeptides (Examples; Figures 1-2). The specification also teaches that the ABCL polypeptides of the invention bear a high homology to the ABC1 subfamily (ABC1, ABC2, ABC-C, and ABCR) (page 85, lines 25-29; figure 5). Specifically, the ABCL polypeptide of SEQ ID NO:5 is 54% identical to ABC1 (see page 85, lines 25-29; Figure 5). Thus, based on the totality of the evidence, one of ordinary skill in the art would find the asserted utility, *i.e.*, the use to treat, diagnose, ameliorate, or prevent a number of diseases, disorders, or conditions associated with ABC transporter polypeptides, to be believable. Furthermore, a person of ordinary skill in the art, recognizing that the disclosed invention is a member of the ABC transporter family, would accept that it is currently available for use as an ATP-dependent transporter. Thus,

applicants contend that the asserted utility is credible to one of ordinary skill in the art, and satisfies the third prong of a utility analysis.

Applicants respectfully submit that because the instant application contains an assertion of a specific and substantial utility for the claimed invention that would be credible to one of skill in the art, the rejection under 35 U.S.C. § 101 should be withdrawn.

B. Claims 9, 13-17, 38-43, 47, and 48 stand rejected under 35 U.S.C. § 112, first paragraph, asserted to not be supported by a specific and substantial asserted utility for reasons set forth in the rejection under 35 U.S.C. § 101 above. The Office further notes that a statement is required that indicates the novel biological materials of the invention have been deposited under the Budapest Treaty and that the biological materials will be irrevocably released to the public upon issuance of a patent. Applicants respectfully disagree with the rejection.

As to the assertion that the claims are not supported by a specific and substantial asserted utility under 35 U.S.C. § 112, first paragraph, Applicants reiterate and adopt the arguments made above in Section IV. A, for the purposes of the § 112, first paragraph utility rejection.

Pursuant to the Examiner's request regarding the deposit of novel biological materials, Applicants' representative submits the following statement: Applicants deposited cDNA, subcloned into pCR2.1, encoding human ABCL polypeptide (Accession No: PTA-3111 (ABCL1550); PTA-3110 (ABCL)), and cDNA subcloned into pCR2.1, encoding murine ABCL polypeptide (Accession No.: PTA-3109) with the American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, VA 20110-2209. The deposit was accepted by the ATCC, an International Depository Authority, under the provisions of the Budapest Treaty. A copy of the ATCC invoice receipt for this deposit, showing the patent deposit designation, (Accession Nos. PTA-3109, PTA-3110, & PTA-3111), and the date on which the deposit was received by the ATCC (March 2, 2001) is attached. Pursuant to 37 C.F.R. § 1.808(a)(2), the deposit was made under conditions that assure that all restrictions imposed by the depositors on the availability to the public of the deposited material would be irrevocably removed upon the granting of a patent relying on the deposited biological material. In making the deposit, Applicants acknowledged their responsibility, pursuant to 37 C.F.R. § 1.805, to provide a replacement or supplemental deposit if the depository possessing the deposit is unable to furnish samples thereof or is able to furnish samples thereof but the deposit has become contaminated or has lost its capability to function as described in the specification.



With regard to the assertion that the date of the deposit and the complete name and address of the depository is not referred to in the body of the specification, Applicants respectfully direct the Examiner's attention to page 80, lines 24-27 of the specification, where Applicants disclose that information. Applicants believe that all the requirements of 37 C.F.R. §§ 1.801-1.809 are met. *In re Lundak*, 225 U.S.P.Q. 90 (Fed. Cir. 1985). Withdrawal of this rejection is therefore respectfully solicited.

#### **IV. Written Description Rejections under 35 U.S.C. § 112, first paragraph.**

Claims 9, 13-17, 38-9, and 41-3 stand rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement. The Office essentially asserts that the written description is insufficient to support the numerous polypeptide sequences recited in the claims, does not provide description of the claimed polypeptide's biological activity/function, and that the claimed polypeptides are defined only by sequence identity rather than function, structure, or explicit sequence.

Applicants respectfully disagree with the Action's assertion that the claims fail to convey with reasonable clarity to those skilled in the art that, as of the filing date, Applicants were in possession of the claimed invention.

Claim 13 provides ample clarity to those of skill in the art that Applicants possessed the amino acid sequence as set forth in SEQ ID NO:5 and the amino acid sequence encoded by the DNA insert in ATCC Deposit No PTA-3111. Thus, the written description requirement for claim 13 is adequately fulfilled by the disclosure of SEQ ID NO: 5, and the deposit of ATCC No PTA-3110.

Claim 14 relates to an isolated polypeptide selected from the group consisting of the amino acid sequence of SEQ ID NO: 6; the amino acid sequence for an ortholog of SEQ ID NO: 5; the amino acid sequence at least 70% identical to SEQ ID NO: 5; a fragment of SEQ ID NO: 5 comprising at least 25 contiguous amino acids of, and comprising the activity of, SEQ ID NO: 5; the amino acid sequence for an allelic or splice variant of SEQ ID NO: 5, ATCC Deposit No PTA-3110. Applicants contend that because the specification explicitly teaches the amino acid sequence for murine and human ABCL polypeptide (Figures 1 and 2), the specification inherently discloses fragments of murine and human ABCL polypeptide, since fragments are merely portions of the specifically disclosed full-length murine and human ABCL polypeptide sequences. Further, Applicants have disclosed an exemplary embodiment of an ortholog of the polypeptide of SEQ ID NO: 5 (human) in Example 3 where the murine ortholog of SEQ ID NO: 5 is cloned, isolated, and sequenced. As noted above, Applicants also provide detailed description

of how one of skill can determine percentage identity of a sequence with the sequence of SEQ ID NO: 5, and how amino acid sequences biological function can be identified in an amino acid sequence using various analysis software. Thus, the application fulfills the written description requirement.

Furthermore, Applicants contend that the Action provides no support for the assertion that the description of a polypeptide sequence (such as that provided in the instant specification in SEQ ID NO: 5) is insufficient to support a claim to fragments of that sequence. Applicants contend that in view of the explicitly-disclosed sequences provided by the instant application, one of ordinary skill in the art could readily determine the structure of amino acid molecules that are fragments of the polypeptide of SEQ ID NO: 5 or the polypeptide encoded by the DNA insert of ATCC Deposit No. PTA-3111, and would recognize that Applicants were in possession of the claimed invention.

Applicants, therefore, submit that the claims satisfies the written description requirement of 35 U.S.C. § 112, first paragraph, and request reconsideration and withdrawal of this rejection.

#### **VI. Rejections of claims under 35 U.S.C. § 102.**

Claims 9, 14-17, and 41 stand rejected under 35 U.S.C. § 102(b), alleged as being anticipated by Database PIR-79, Accession No. A54774, April 5, 1995 (Luciani, et al.). Specifically, the Office asserts that Luciani discloses a polypeptide that has 49.6% identity to the polypeptide of SEQ ID NO: 5, and a fragment of at least about 25 amino acid residues of SEQ ID NO: 5. Applicants respectfully disagree.

According to MPEP § 2131, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.’ *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). ‘The identical invention must be shown in as complete detail as is contained in the...claim.’ *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).”

Claim 14(d) as amended relates in part to an isolated polypeptide comprising the amino acid sequence selected from the group consisting of a fragment of the amino acid sequence set forth in SEQ ID NO: 5 comprising at least about 25 contiguous amino acid residues, wherein the fragment has an activity of the polypeptide set forth in SEQ ID NO: 5...”. The sequence of Luciani does not teach an amino acid sequence that comprises at least 25 contiguous amino acid residues of SEQ ID NO: 5. (See, Alignment page 1a, et seq., provided with Office action, dated February 24, 2005). Further, Luciani fails to teach an amino acid sequence that is at least 70 percent identical to the amino acid sequence of SEQ

ID NO: 5 (claim 14(c)). As noted in the Office action, Luciani discloses a polypeptide asserted to have 49.6 % query match and 49.6 % identity to the polypeptide of SEQ ID NO: 5. While the sequence disclosed by Luciani has some similarity to the ABCL polypeptide of the invention, it does not properly anticipate the invention, as claimed, because it fails to show each and every element of the claimed polypeptide.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of the claims under § 102(b), in view of Luciani.

Claims 9, 14-17, 38-39, and 41 stand rejected under 35 U.S.C. § 102(e), alleged as being anticipated by U.S. Patent 6,617,122 (Hayden, et al.). Specifically, the Office asserts that Hayden discloses a polypeptide that has 50.3% identity to the polypeptide of SEQ ID NO: 5, and a fragment of at least about 25 amino acid residues of SEQ ID NO: 5, wherein the fragment is antigenic. Applicants respectfully disagree.

Hayden fails to anticipate the claimed invention for much the same reasons as detailed above regarding Luciani's failure to anticipate the invention as claimed. In particular, Hayden fails to teach or disclose a fragment of the amino acid sequence set forth in SEQ ID NO: 5, comprising at least 25 contiguous amino acid residues of SEQ ID NO: 5. (See, Alignment page 1 et seq., provided with Office action, dated February 24, 2005). Further, Hayden fails to teach an amino acid sequence that is at least 70 percent identical to the amino acid sequence of SEQ ID NO: 5 (claim 14(c)). As noted in the Office action, Hayden discloses a polypeptide alleged to have 51.8 % query match and 50.3 % identity to the polypeptide of SEQ ID NO: 5. While the sequence disclosed by Hayden has some similarity to the ABCL polypeptide of the invention, it does not properly anticipate the invention, as claimed, because it fails to show each and every element of the claimed polypeptide.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of the claims under § 102(e), in view of Hayden.

## VII. CONCLUSION

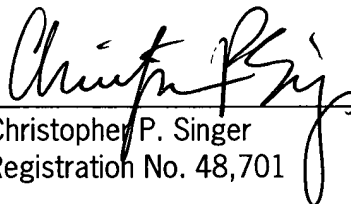
Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited. The Examiner is invited to contact the undersigned representative by telephone at 312-913-0001 to discuss any aspect of this response.

Respectfully submitted,

**McDonnell Boehnen Hulbert & Berghoff LLP**

Dated: July 25, 2005

By: \_\_\_\_\_

  
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